## UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

ASHLY JONES and BASIM JOHNSON,	
Plaintiffs,	Civil Action No.
v.  KENVUE, INC. and JOHNSON & JOHNSON CONSUMER INC.,	CLASS ACTION COMPLAINT AND JURY DEMAND
Defendants.	

#### **CLASS ACTION COMPLAINT**

Plaintiffs Ashly Jones and Basim Johnson hereby bring this class action lawsuit for themselves and on behalf of others similarly situated against Defendants Kenvue, Inc. ("Kenvue") and Johnson & Johnson Consumer Inc. ("JJCI").

#### **INTRODUCTION**

- 1. Plaintiffs bring these claims to redress the economic harms caused by Defendants' sale of acne treatment drug products containing benzoyl peroxide ("BPO") without warning consumers that (1) the BPO in the products is at high risk of degrading, and in fact degrades, into benzene under normal and expected use, handling, and storage conditions, and (2) said products contain benzene, which is a well-known human carcinogen.
  - 2. Defendant Kenvue is a leading global consumer health corporation, formed

when Johnson & Johnson spun off its consumer health healthcare division. Kenvue has several brands under its corporate umbrella including Clean & Clear and Neutrogena. Under these brands, Defendants offers several products to treat acne which contain BPO. The products are Rapid Clear Stubborn Acne Spot Gel, Clear Pore Cleanser/Mask, and On-the-Spot Acne Treatment (collectively the "Products" or "BPO Products").

- 3. The Products are used to treat acne vulgaris ("acne") and are formulated with BPO, along with other inactive ingredients, to make acne treatment creams, washes, scrubs, and bars. Before being sold to the public, the Products must be made in conformity with current good manufacturing practices and must conform to quality, safety, and purity specifications.
- 4. Defendants sell and distribute BPO Products under the brand names Clean & Clear and Neutrogena. According to Defendants, the Clean & Clear and Neutrogena brands are iconic and beloved by consumers. They are premium brands, and the BPO Products the Defendants made, packaged, marketed, and sold under the brands are premium products.
- 5. The Products should not contain benzene, nor degrade into benzene, except under an extraordinary allowance unavailable to the BPO Products.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> See Food and Drug Administration, Q3C – Tables and List Guidance for Industry at p. 5, https://www.fda.gov/media/71737/download ("Solvents in Class 1 (Table 1) should not be employed in the manufacture of drug substances, excipients, and drug products because of their unacceptable toxicity or their deleterious environmental effect. However, if their use is

#### **PARTIES**

- 6. Plaintiff Ashly Jones, an adult resident of St. Louis County, Missouri, resided in Kansas City, Missouri, when she purchased and used the BPO Products in Missouri for many years. She moved from Kansas City to St. Louis in 2022. She has suffered economic harm from Defendants' breaches and wrongful conduct, as alleged, including (but not limited to) their violations of the consumer protection law alleged herein. Plaintiff Jones never would have purchased Defendants' BPO Products had Defendants warned about the presence of benzene or that their products could degrade into benzene.
- 7. Plaintiff Basim Johnson, an adult resident of St. Louis County, Missouri, resided in Kansas City, Missouri, when he purchased and used the BPO Products in Missouri for many years. He moved from Kansas City to St. Louis in 2022. He purchased and used the Products that are marketed, packaged, and labeled as containing 10 percent BPO. He has suffered economic harm from Defendants' breaches and wrongful conduct, as alleged, including (but not limited to) their violations of the consumer protection law alleged herein. Plaintiff Johnson never would have purchased Defendants' BPO Products had Defendants warned about the presence of benzene or that their products could degrade into benzene.

unavoidable in order to produce a drug product with a significant therapeutic advance, then their levels should be restricted as shown in Table 1, unless otherwise justified."). Per the FDA's guidance, the amount of benzene in a product should be less than 2 parts per million. *Id*.

- 8. Defendant Kenvue is incorporated in Delaware. It is a citizen of New Jersey with its principal place of business at 199 Grandview Road, Skillman, New Jersey 08558.
- 9. Kenvue reports earnings from the Neutrogena and Clean & Clear brands under its own name, not the name of an affiliate or subsidiary. It trademarks the BPO Products. The BPO Products are packaged, advertised, and sold with the trademarks.
- 10. Defendant JJCI is an indirect, wholly-owned subsidiary or affiliate of Kenvue. It is incorporated in Delaware and has its principal place of business in Skillman, New Jersey.
- 11. At all relevant times, the Defendants conducted business and derived substantial revenue from their manufacturing, advertising, marketing, distributing, and selling of the BPO Products within the State of Missouri and in this District.
- 12. Defendants and their agents promoted, marketed, and sold the BPO Products in Missouri and in this District. The unfair, unlawful, deceptive, and misleading advertising and labeling of the Products were prepared and/or approved by Defendants and their agents and were disseminated by Defendants and their agents through labeling and advertising containing the misrepresentations alleged and disseminated uniformly through advertising, packaging, containers, websites, and social media.

#### **JURISDICTION AND VENUE**

13. This Court has jurisdiction over this matter because the parties are diverse and the amount in controversy exceeds \$5 million, satisfying 28 U.S.C. § 1332(d)(2) for

subject matter jurisdiction. This Court has supplemental jurisdiction over any state law claims under 28 U.S.C. § 1367.

- 14. Venue is proper in this District under 28 U.S.C. § 1391(b), because a substantial part of the events or omissions giving rise to the claims occurred in this District, including the Plaintiffs' purchases and personal use of the Products. The Plaintiffs lived in this District at that time, and at that time, the Defendants conducted business in this District. They continue to do so.
- Defendants transact business in this District, have substantial aggregate contacts with the State of Missouri, including in this District, and have engaged in misconduct in this District that has had a direct, substantial, reasonably foreseeable, and intended effect of injuring people in the State of Missouri and in this District. Defendants purposely availed themselves of the benefits of doing business in the State of Missouri and in this District. The Defendants maintained a registered agent for service in this State at the time of the Plaintiffs' purchases of the Products in this District.

#### **REGULATION**

16. Throughout this Complaint, references to federal law and FDA regulation are merely to provide context and are not intended to raise a question of law. All claims alleged in this Amended Complaint arise out of violations of state law, which in no way conflict, interfere with, or impose obligations that are materially different than those

imposed by federal law.

- 17. Most federal regulation of pharmaceuticals is conducted pursuant to the Food, Drug, and Cosmetic Act ("FFDC") (21 U.S.C. §§ 301 et seq.), with the FDA as the principal regulator. At a high level, the goal of the FDA's regulation of drugs is to ensure the safety and effectiveness of pharmaceuticals for consumers.
- 18. Two regulatory pathways exist to bring an OTC—an "over-the-counter" or non-prescription—drug to market: (1) the New Drug Application ("NDA") and (2) the OTC Drug Review process, also known as the monograph system.
- 19. The NDA process regulates the approval for marketing and sale of new pharmaceuticals, such as name-brand drugs like Xanax or Lipitor. Generic-brand drugs are governed by the corollary Abbreviated New Drug Application ("ANDA") process.
- 20. The monograph system, by contrast, is not for new OTC drugs. Established in 1972, the monograph system was designed to regularize the marketing and sale of drugs that were already being marketed before May 11, 1972. For monograph drugs, a drug-specific approval process was not necessary.
- 21. Acne products containing BPO are governed by the monograph system. As set forth further below, there are meaningful differences between the NDA process and the monograph system.
  - 22. The NDA Process is heavily regulated and requires FDA preapproval of

any drug label before a drug can be brought to market.<sup>2</sup>

- 23. FDA's approval of an NDA before the drug is brought to market includes approval of the *exact text* of the proposed label.<sup>3</sup>
- 24. Once the FDA issues a formal approval letter, a drugmaker can begin marketing the drug using *only* the *exact* text from the approved label. And once that approval occurs, the drugmaker cannot unilaterally make most types of label changes. Indeed, federal regulations prohibit most types of changes to an NDA label without FDA preapproval of a supplemental application.<sup>4</sup>
  - 25. There is an exception to this general rule for NDA drugs called the "changes

<sup>&</sup>lt;sup>2</sup> 21 U.S.C. §§ 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."); 355(b)(1) (enumerating the materials required to be submitted with such an application, including "(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use; (ii) a full list of the articles used as components of such drug; (iii) a full statement of the composition of such drug; (iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (v) such samples of such drug and of the articles used as components thereof as the Secretary may require; (vi) specimens of the labeling proposed to be used for such drug; (vii) any assessments required under section 355(c) of this title; and (viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug. . . .").

<sup>&</sup>lt;sup>3</sup> See 21 U.S.C. § 355; 21 C.F.R. § 314.105(b) ("FDA will approve an NDA and issue the applicant an approval letter on the basis of draft labeling if the only deficiencies in the NDA concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.").

<sup>&</sup>lt;sup>4</sup> 21 C.F.R. § 314.70(b) (prohibiting most types of changes to an NDA label without FDA preapproval of a supplemental application).

being effected"—or CBE—regulation.<sup>5</sup> Pursuant to the CBE regulations, an NDA holder may unilaterally *strengthen* the label's warnings and precautions—without FDA preapproval—based on "newly acquired information."<sup>6</sup> If the FDA does not believe the CBE regulation has been satisfied, however, it can subsequently reject that labeling change.<sup>7</sup>

- 26. ANDA manufacturers—i.e., those who manufacture generic drugs comparable in dosage, form, strength, route of administration, quality, performance characteristics, and intended use to a name-brand drug—have even less latitude to change their labels without FDA preapproval. ANDAs are approved after the FDA determines that the generic product matches exactly the product of an NDA holder in all relevant respects. By regulation, an ANDA holder's warning label must match the NDA holder's label verbatim.<sup>8</sup>
- 27. This means that, under the NDA system, ANDA holders cannot avail themselves of the CBE regulation to unilaterally strengthen warnings or precautions even in the face of new information.

<sup>&</sup>lt;sup>5</sup> 21 C.F.R. § 314.70(c)(3).

<sup>&</sup>lt;sup>6</sup> 21 C.F.R. § 314.70(c)(6)(iii) ("The agency may designate a category of changes for the purpose of providing that, In the case of a change in such category, the holder of an approved NDA may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change. These changes include, but are not limited to . . . [c]hanges in the labeling to reflect newly acquired information. . . .").

<sup>&</sup>lt;sup>7</sup> *Id*.

<sup>&</sup>lt;sup>8</sup> See 21 U.S.C. § 355(j)(2)(A)(v); 21 U.S.C. § 355(j)(4)(G); 21 C.F.R. § 314.94(a)(8); 21 C.F.R. § 314.127(a)(7).

- 28. The monograph system operates differently. Marketers of monograph OTC drugs do not submit a premarketing application with a label that FDA then approves.<sup>9</sup>
- 29. Indeed, the FDA *never even reviews* a monograph drug's label. There is no monograph equivalent to 21 C.F.R. § 314.0(b) which requires FDA preapproval to alter an OTC label after a monograph drug is on the market so, of course, there is no CBE exception to that nonexistent general rule.<sup>10</sup>
- 30. Instead, under the monograph system, the FDA issues a comprehensive regulation—a monograph—for each therapeutic class of OTC drugs, setting out each drug's FDA-approved active ingredients and then identifying the conditions under which the rugs are generally recognized as safe and effective. This system regulates by class of drug rather than by individual drug. Under the monograph system, there are no "generic" drugs operating under a modified regulatory framework under the monograph system. Different brand names, such as Neutrogena or Clearasil, are governed by the same rules. The makers of each brand are equally deemed "marketers" under the applicable regulations. <sup>12</sup>

<sup>&</sup>lt;sup>9</sup> See Over-The-Counter Human Drugs; Labeling Requirements, 64 Fed. Reg. 13,254, 13,271 (Mar. 17, 1999) ("Products that are marketed under an OTC drug monograph are not required to submit labeling to the agency for preapproval.").

<sup>&</sup>lt;sup>10</sup> Compare 21 C.F.R. § 330.1 with 21 C.F.R. § 314.70(b).

<sup>11</sup> Id.

<sup>&</sup>lt;sup>12</sup> 21 C.F.R. § 330.13(b)(2) ("Marketing of such a product with a formulation or labeling not in accord with a proposed monograph or tentative final monograph also may result in regulatory action against the product, the marketer, or both.").

- 31. As a consequence, all OTC drug marketers are treated equally and have the ability to unilaterally change their labels. There is no distinction under the regulatory regime between, for instance, JJCI/Kenvue—the marketer of Neutrogena-branded BPO Products—and Walmart, Inc.—the marketer of Equate-branded BPO Products. Both sets of marketers have a duty to update the drug's label to account for risks under the regulatory regime and state law.
- 32. One distinction between the monograph and NDA regulatory schemes is particularly salient. Because a drug's OTC monograph does not specify the exact label which must be used with respect to a particular drug, marketers must use their professional judgment to create packaging that complies with FDA's regulations. Thus, unlike with the NDA system, marketers of monograph drugs can unilaterally make changes to the warning label as long as those changes do not conflict with the warnings required by applicable regulations that carry the force of law.
- 33. In accord with this system, the monograph that governs BPO is covered under a more general monograph for Acne treatments. It states at the outset that "An over-the-counter acne drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this [monograph] and each general condition established in § 330.1 of this chapter." <sup>13</sup>
  - 34. The Acne Treatment Monograph goes on to list active ingredients and

<sup>&</sup>lt;sup>13</sup> Topical Acne Drug Products, 56 FR 41019, Aug. 16, 1991 ("Acne Treatment Monograph").

define the percentage of those active ingredients which, if included in the product, cause the monograph to apply to it.<sup>14</sup> Included in this list is benzoyl peroxide, with a range of "2.5 to 10 percent."<sup>15</sup> Therefore, any product whose ingredient composition is 2.5 to 10 percent BPO is covered by the Acne Treatment Monograph.

- 35. The Acne Treatment Monograph does not list benzene as an approved active ingredient for acne treatment products.<sup>16</sup>
- 36. The Acne Treatment Monograph lists certain warnings which covered products, including BPO Products, must contain on their labeling. Some of these warnings apply to all acne treatment products<sup>17</sup> while other warnings apply specifically to acne treatment products containing BPO.<sup>18</sup>
- 37. The Acne Treatment Monograph also mandates the inclusion of certain directions related to the use of acne treatment products<sup>19</sup> including specific directions for products containing BPO.<sup>20</sup>
- 38. The Acne Treatment Monograph does not mandate any warnings or directions related to the storage of acne treatment products, including acne treatment products containing BPO.

<sup>&</sup>lt;sup>14</sup> 21 CFR §333.310.

<sup>15 §333.310(</sup>a).

<sup>&</sup>lt;sup>16</sup> See id.

<sup>&</sup>lt;sup>17</sup> §333.350(c)(1).

<sup>&</sup>lt;sup>18</sup> §333.350(c)(4).

<sup>&</sup>lt;sup>19</sup> §333.350(d)(1).

<sup>&</sup>lt;sup>20</sup> §333.350(d)(2).

- 39. Absent from the Acne Treatment Monograph's warning section is any language suggesting that the required warnings are exclusive. Accordingly, marketers such as Defendants retain the regulatory freedom to provide additional, truthful warnings which do not contradict the warnings required by federal law. Further, marketers of acne treatment products have the duty to use their professional judgment to create packaging which both complies with federal regulations and provides potential users with adequate warnings of the risks associated with the use of those products.
- 40. Despite the fact that federal law did not prohibit Defendants from including warnings about the risk that the BPO in their products may degrade to benzene under normal use and storage conditions, they nevertheless failed to include any such warnings on their BPO Products.

#### BENZENE IN THE DEFENDANTS' PRODUCTS

- 41. Though not commonly known or understood by the public, BPO has long been known and understood within the scientific community to degrade into benzene.<sup>21</sup>
- 42. Benzene is a known human carcinogen. There is a well-established consensus within the medical and scientific community that benzene exposure, even in low amounts, increases the risk of blood cancers and other adverse effects.
  - 43. There is no safe level of benzene exposure to humans, and FDA guidance

<sup>&</sup>lt;sup>21</sup> Erlenmeyer, H. and Schoenauer, W. (1936), Über die thermische Zersetzung von Di-acylperoxyden. HCA, 19: 338-342. https://doi.org/10.1002/hlca.19360190153 (https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153) (accessed 6/6/2024).

specifies that drug products should not contain benzene due to its unacceptable toxicity, and that benzene is permissible up to 2 ppm only for products which require benzene for their manufacture. That extraordinary allowance does not apply to the BPO Products.

- 44. All the BPO Products marketed and sold by the Defendants decompose into benzene rendering them materially different than advertised in that they contain benzene, a carcinogen and known risk to human health.
- 45. In 2023, Valisure, LLC (an independent, accredited laboratory that has developed analytical methods for testing consumer products for public safety) tested a representative sample of BPO and non-BPO products and found that the BPO Products had dangerous levels of benzene, many multiple times higher than the 2 ppm permitted for products which require benzene for their manufacture (which is not the case for these products).<sup>22</sup>
- 46. Valisure tested "Neutrogena 10% BPO cleanser" and "Clean & Clear 10% BPO cleanser." <sup>23</sup>
- 47. "Neutrogena 10% BPO cleanser" and "Clean & Clear 10% BPO cleanser" are BPO products of the Defendants. To test them for benzene, Valisure exposed them to a temperature of 98.6 degrees Fahrenheit (37 Celsius). Research Letter at Figure 1(A). Benzene was detected in the two Products at the start of the exposure and steadily

<sup>&</sup>lt;sup>22</sup> See Valisure's FDA Citizen's Petition on Benzoyl Peroxide (March 6, 2024).

<sup>&</sup>lt;sup>23</sup> <a href="https://ehp.niehs.nih.gov/doi/10.1289/EHP13984">https://ehp.niehs.nih.gov/doi/10.1289/EHP13984</a> (Research Letter, "Benzoyl Peroxide Drug Products Form Benzene") (hereinafter "Research Letter") (accessed 6/6/2024).

increased afterward. *Id.* It reached levels exceeding 20 ppm at points between 25 and 28 days of exposure. *Id.* 

- 48. To test "shelf-life performance," Valisure exposed the same two products of the Defendants to a higher temperature of 122 degrees Fahrenheit. This testing revealed benzene levels above 900 parts per million (ppm) at 28 days of exposure. Research Letter at Figure 1(B).
- 49. BPO acne treatments of other companies were tested by Valisure, with results similar to the BPO Products of the Defendants, namely benzene detected at the start of exposure which increased as the time of exposure increased. *See* Research Letter & Fig. 1. These other products contained BPO in amounts from 2.5 percent to 10 percent, according to their packaging. *See Id*.
- 50. In the non-BPO products exposed and tested by Valisure, benzene was not present, even at trace levels.
- 51. The benzene in the Defendants' BPO Products at the start of exposure in the Valisure test is evidence that all BPO Products purchased by the Plaintiffs and Class contain benzene. It is circumstantial proof that benzene is present in the products when they are purchased, due to normal and expected temperature exposure during manufacturing, packaging, storage, shipping, and distribution.
- 52. Defendants have never listed benzene among the ingredients or anywhere on the BPO Products' labels, containers, advertising or on their websites, despite the fact

that the BPO Products contain benzene and have a proven propensity to degrade into ever-increasing amounts of benzene. Defendants never warned that the Products were at risk of benzene contamination. This is, of course, unsurprising, as such a disclosure would have devastated the sales of the Products.

53. In many instances, the Defendants' BPO Products instruct consumers to store the products at a temperature no greater than 77 degrees Fahrenheit. The Defendants warn consumers about "heat" this way: "Other Information Protect from Excessive Heat (40 °C/104 °F)." That warning appears on the product label as follows:

# Other information Protect from Excessive Heat (40°C/104°F)

Label of a 10% BPO Neutrogena Product 24

- 54. This warning is grossly inadequate. It warns consumers that product exposure at 104 °F is excessive, but is silent on the consequences of that exposure or exposure at any temperature below 104 °F. It discloses nothing about what can occur if storage temperature exceeds 77 °F. The warning is inadequate for those reasons and because the Defendants' BPO Products relentlessly degrade into benzene at exposure of no more than 98.6 degrees (Research Letter at Figure 1(A)), which is lower than the 104 °F. the Defendants define as excessive.
  - 55. The warning to avoid exposure at 104 °F shows that the Defendants knew

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https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=5b11b2de-d156-4d6a-8024-0a945661cd9a (accessed 6/6/2024).

and foresaw that their BPO Products would be exposed to temperatures above 98.6 degrees (the lowest Valisure test temperature) and well above the 77 °F storage instruction. It shows that the Defendants, based on that knowledge, could have warned consumers that (1) expected heat exposure would degrade the BPO Products into benzene, and (2) that benzene is a carcinogen and unsafe. No such warnings were made. The Products disclose nothing on the subject.

- 56. The instruction to consumers (to the extent given) to store the BPO Products at a temperature no greater than 77 °F is inadequate for the foregoing reasons.
- 57. The warning to avoid excessive heat, defined by Defendants as 104 °F, is not required by the FDA monograph for the BPO Products. That warning, inadequate as it is, shows that no regulation of the BPO products under a FDA monograph prevented the Defendants from warning consumers of benzene from expected heat exposure of the BPO products. The Defendants could have packaged, advertised, and labeled the Products with adequate warnings, but did not.
- 58. Defendants, as marketer, developer, manufacturer, and/or distributor of the Products, knew or should have known that the BPO Products contain benzene and would further degrade into benzene from expected heat exposure.
- 59. Defendants knew or should have known that the BPO used in their products would degrade into benzene. But in no instance did the Defendants warn consumers that their BPO Products can degrade into benzene, or that benzene is a

carcinogen and unsafe.

- 60. Defendants misled Plaintiffs, the Class, and the public by representing the Products only had the ingredients listed and—by omission—did not contain benzene.
- 61. Defendants also misled Plaintiffs, the Class, and the public by representing the Products were safe while concealing material health and safety information known to them, primarily that the Products either contained benzene or would degrade to benzene under normal consumer conditions.
- 62. Defendants further misled Plaintiffs, the Class, and the public by giving the BPO Products long expiration dates of 2-3 years, affirming to consumers that the Products were safe for use for years, when Defendants knew or should have known that the BPO in the products would degrade into benzene far sooner than that, including by the time of purchase.
- 63. Defendants' statements and omissions of material health and safety information unreasonably placed Plaintiffs, the Class, and the public at risk of exposure to benzene without their knowledge and consent. Defendants' statements about the Products were not only false and misleading, but they were also blatantly and intentionally deceptive.
- 64. As a result of Defendants' misconduct and consumer deception, the Plaintiffs, the Class, and the public have been economically harmed, as they purchased a product—one containing a deadly human carcinogen—that they otherwise would never

have purchased.

- 65. This Class Action is necessary to redress harms caused to Plaintiffs, and Class members who bought the BPO Products, believing them to be safe and high quality and only containing the ingredients listed on the Products' labels, containers, advertisement, and on Defendants' websites. This Class Action is further necessary to expose Defendants' ongoing consumer fraud and to enjoin Defendants from continuing their misconduct and deception to protect the public.
- 66. Plaintiffs bring this Class Action on behalf of themselves, and on behalf of those similarly situated, and seek to represent a Class of Consumers who purchased Defendants' BPO Products in Missouri. Plaintiffs seek damages, reasonable attorneys' fees and costs, interest, restitution, other equitable relief, including an injunction and disgorgement of all benefits and profits Defendants received through their misconduct.

#### **GENERAL ALLEGATIONS**

#### A. Benzene Is a Deadly Carcinogen with No Safe Exposure Level.

67. Benzene is a carcinogen that has been among the most studied toxins over the last 100 years due to its wide use during the industrial revolution, extreme danger, and known ability to cause cancer and death in humans and animals. The medical literature linking benzene to blood cancers is vast dating to the 1930s.<sup>25</sup>

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<sup>&</sup>lt;sup>25</sup> See Hamilton A., Benzene (benzol) poisoning, ARCH PATHOL, (1931):434-54, 601-37; Hunter FT, Chronic exposure to benzene (benzol). Part 2: The clinical effects. J. IND. HYG TOXICOL, (1939):21 (8)

- 68. Benzene has no known safe level of exposure. Benzene causes central nervous system depression and destroys bone marrow, leading to injury in the hematopoietic system. The International Agency for Research on Cancer ("IARC") classifies benzene as a "Group 1 Carcinogen" that causes cancer in humans, including acute myelogenous leukemia ("AML"). AML is the signature disease for benzene exposure with rates of AML particularly high in studies of workers exposed to benzene.
- 69. Benzene exposure is cumulative and additive. There is no safe level of exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion." According to the FDA, benzene in small amounts over long periods of time can decrease the formation of blood cells and long-term exposure through inhalation, oral intake, and skin absorption may result in cancers such as leukemia and other blood disorders.
- 70. In 2022, the FDA issued a safety alert warning manufacturers of the risk of benzene contamination in certain products and components.<sup>26</sup> The FDA warned manufacturers that if any product or component was subject to deterioration, manufacturers must have re-testing procedures in place to ensure continued purity and

<sup>331-54;</sup> Mallory TB, et al., Chronic exposure to benzene (benzol).Part 3:The pathological results. J. IND. HYG TOXICOL,(1939):21 (8) 355-93; Erf LA, Rhoads CP., The hematological effects of benzene (benzol) poisoning. J. IND. HYG TOXICOL, (1939):21 421-35; American Petroleum Institute, API Toxicological Review: Benzene, NEW YORK, (1948); Infante PF, Rinsky RA, Wagoner JK, et al., Leukemia in benzene workers, LANCET, (1977);2 (8028): 76-78.

<sup>&</sup>lt;sup>26</sup> Federal Drug Administration. (Dec. 22, 2022). FDA Alerts Drug Manufacturers to the Risk of Benzene in Certain Drugs.

stability of the degradable components. If any product in circulation was found to have benzene over 2 ppm, the FDA directed that drug manufacturers contact the FDA to discuss a voluntary recall.

71. To date, none of the Defendants' Products containing BPO have been recalled due to benzene contamination.

## B. <u>Defendants' Marketing of Their BPO Products.</u>

- 72. Defendants' BPO Products are widely marketed, available, sold, and used by children, teenagers, and adults throughout the United States and the world. The acne treatment industry is a multi-billion-dollar market. In order to remain competitive and relevant within this industry, Defendants spend millions of dollars promoting their Products directly to consumers, including younger consumers, such as teenagers. Defendants make use of social media sites to promote their Products.
- 73. Defendants make promises to consumers to influence their purchasing decisions such as affirming the Products are tested, backed by science, and approved by dermatologists. Defendants told consumers they should buy the Products because Defendants are a market leader and acne expert which cares about consumers and the environment and sells only safe and tested Products.
- 74. Defendants describe Clean & Clear as a "brand that listens" to their consumers and "constantly work[s] to improve skin care through technology, innovation,

and new and improved formulas."<sup>27</sup> They tout their "65+ years of skincare experience" and describe themselves as an "industry leader . . . playing an active role in the evolution of skincare."<sup>28</sup>

75. Defendants, through the Neutrogena brand, tout their scientific expertise, stating that "we rely on our scientists, dermatologists and skin experts to create inclusive products that meet all unique needs, so you can always find science-backed skin care that's right for you."<sup>29</sup> Defendants promises that "[a]ll our ingredients are carefully selected to be safe . . . ."<sup>30</sup>

#### C. <u>Defendants Did Not Adequately Test Their Products for Benzene.</u>

76. Defendants did not adequately test their Products before selling them to Plaintiffs, the Class, and the public. Defendants were required to follow current good manufacturing practices ("CGMPs"), have scientifically sound specifications, and must have test procedures and processes to ensure the Products' components (both active and inactive ingredients), and finished products are safe. Both raw ingredient materials and finished batches must be tested before released to the public to confirm that they meet specifications for identity, strength, quality, and purity.<sup>31</sup> If testing results of either the raw materials or the finished products do not conform with the specifications, the product

<sup>&</sup>lt;sup>27</sup> https://www.cleanandclear.com/about-clean-clear (last accessed 3/21/2024).

<sup>&</sup>lt;sup>28</sup> *Id*.

<sup>&</sup>lt;sup>29</sup> https://www.neutrogena.com/navigation/about/about-us.html (last accessed 3/21/2024).

<sup>&</sup>lt;sup>30</sup> *Id*.

<sup>&</sup>lt;sup>31</sup> 21 C.F.R. § 211.84 (1978); see also 21 C.F.R. § 211.160 (1978)

cannot be sold to the public. Defendants must also re-test any Products which are subject to deterioration.<sup>32</sup>

- 77. Defendants must also do stability testing to understand the "shelf life" of the Products and to assign an appropriate expiration date. It is well known that certain chemical ingredients can degrade or change because of environmental and storage conditions, such as light, moisture, temperature, and humidity, or simply do to the passage of time. The required stability testing should cover all expected distributor and consumer storage, handling, and use conditions and must be done using "reliable, meaningful, and specific test methods." If stability testing finds a drug product is not stable under expected storage or use conditions, degrades, or creates toxic byproducts, the product cannot be sold to the public.
- 78. The CGMPs and stability test requirements are there to ensure products are safe for public use. Therese are the minimum requirements. Because the manufacturers are self-regulated, the FDA—and the consumers of the products— must rely on drug manufacturers, the public, and concerned citizens to report unsafe products.
- 79. Defendants knew or should have known that the BPO in their Products degrades to benzene. Defendants knew that, because the chemical nature of BPO is not stable and would degrade when exposed to the environmental temperatures found in

<sup>&</sup>lt;sup>32</sup> 21 C.F.R. § 211.160(b)(1)(1978).

<sup>33 21</sup> CFR 211.166.

normal distributor and consumer use, handling, and storage conditions.

- 80. The degradation of BPO to benzene over time when exposed to heat has been well known for some time, and the process has been reported in the scientific literature as early as 1936.<sup>34</sup>
- 81. The degradation of BPO to benzene was known or should have been known to Defendants, who promote themselves as dedicated to science and research. Defendants market themselves as world class acne drug researchers, developers, and manufacturers. Defendants employed high-level scientists, chemists, and researchers to formulate their drug products for public use. Defendants with these resources and expertise were aware of the well-known chemical processes through which the BPO in their products would degrade into benzene when exposed to common use temperatures and conditions.
- 82. Defendants knew or should have known through their own research, development, formulation, manufacturing, and testing whether the BPO in their Products was chemically and physically stable. Defendants was required not only to adequately test the BPO Products for safety and stability before selling them to the public, but also to monitor their internal practices, processes, and specification to make sure they kept pace with science and emerging methodologies. Defendants knew or should have known from expiration and stability studies examining the "shelf life" of the Products that the

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<sup>&</sup>lt;sup>34</sup> H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden*, HELU. CHIM. ACTA, 19, 338 (1936).

degradation of BPO to benzene took place because of normal and expected environmental, use, and storage conditions.

- 83. Defendants knew or should have known the Products would be handled, used, and stored by distributors, sellers, and consumers under various temperatures that affect chemical stability. Defendants knew or should have known the Products would travel by commercial carriers and distributors in varying storage conditions and would be stored by consumers in handbags, backpacks, bathrooms, showers, lockers, and in vehicles during warm months where the Products would be exposed to heat.
- 84. Defendants knew or should have known that consumers would apply the benzene contaminated Products to their faces and bodies and would also use the Products in heated showers as scrubs and washes. Defendants knew or should have known that the Products would be used and applied to the skin at normal body temperatures, and elevated temperatures following showers, baths, after physical activity, and after the Products sat in warm temperatures or hot vehicles.
- 85. The storage, use, and handling conditions of the Products were known or should have been known to Defendants before their Products containing BPO were marketed and sold to Plaintiffs and Class members. Defendants knew or should have known that the BPO in these Products would degrade to benzene under these conditions. Defendants further knew or should have known that, because of the known degradation of BPO to benzene, their Products with BPO were contaminated with benzene by the time

they reached consumers, but they sold them to Plaintiffs, the Class, and the public anyway and without any warning of the benzene contained within them.

86. In 2020, the FDA started working with companies to identify benzene in products, which resulted in product recalls of hand sanitizers, sunscreens, and deodorants. Defendants were aware or should have been aware of benzene contamination in other BPO products on the market when they marketed and sold their Products to Plaintiffs, the Class, and the Public, but did not test the Products for benzene contamination.

# D. <u>Defendants exposed Plaintiffs, the Class, and the Public to Benzene without their knowledge or consent.</u>

- 87. Despite the fact that their Products contain benzene, Defendants did not list benzene among the Product's ingredients, on the Products' label or container, or anywhere in their advertising or on their websites. Defendants did not—and still does not—warn that the Products contain benzene, are at risk of benzene contamination, or that the product could cause consumers to be exposed to benzene even while the product remains sealed.
- 88. As noted above, benzene is a known human carcinogen which is heavily regulated to protect human health, and should not be in drug products, especially ones such as acne treatment which are used daily by children and teenagers for many years. FDA specifically prohibits benzene from being used to make products because any "benefit" it may impart is vastly outweighed by its toxicity and harmful environmental

effects. FDA allows one exception to this otherwise blanket prohibition, and that is when the use of benzene in a product is unavoidable, and the product has significant therapeutic advantages for the consumer. Even in that rare instance, benzene in a product is restricted to 2 ppm. Defendants' acne treatment products do not meet this rare exception.

- 89. Plaintiffs, members of the Class, and the Public were exposed to benzene from Defendants' BPO Products through inhalation and dermal absorption. Benzene can be absorbed into the body via inhalation, skin absorption, ingestion, and/or eye contact. Plaintiffs and the Class applied Defendants' BPO Products to areas of the skin including face, neck, chest, and back one to three times per day, and used the BPO Products as washes or scrubs in heated showers. Plaintiffs and the Class were also exposed to benzene leaked from contaminated BPO Products.
- 90. Defendants represented to the Plaintiffs, the Class, and the Public that each of their Products had only the ingredients listed on the label and package, but failed to identify benzene anywhere on the Products' label, container, or packaging.
- 91. Defendants made many representations as to the safety of their BPO Products. It stated that "safety starts with ingredients" and warrants that "[o]ur ingredients are screened for quality, manufacturing process, government regulations, published research, and our own ingredient safety databases." Defendants also states

<sup>35</sup> https://www.kenvue.com/our-commitments (last accessed 3/21/2024).

that "[s]afety doesn't end with placing the products on the shelf" and that "[o]ur experts are continuously monitoring and adjusting the process based on the latest research, guidance, regulations, customer, and consumer feedback."<sup>36</sup>

- 92. Finally, Defendants acknowledges that "[s]cience isn't set in stone," promises that "we continually check the latest data on our ingredients," and promises that "[w]hen necessary we update our products to make sure they are still safe."<sup>37</sup>
  - 93. Defendants have described BPO as "safe." 38
  - 94. Defendants have referred to BPO as a "miracle." 39
- 95. Defendants' statements about the BPO Products' ingredients were false, deceptive, and misleading. Defendants' statements were meant to convey to Plaintiffs, the Class, and the public the message that the BPO Products were safe and did not contain carcinogens, such as benzene. Defendants made these statements and omitted benzene from all advertising, labeling, and packaging when they knew or should have known the statements were false, misleading, and deceptive. Reasonable consumers, relying on Defendants' statements reasonably believed the BPO Products were safe and did not contain benzene.

<sup>37</sup> *Id*.

<sup>&</sup>lt;sup>36</sup> *Id*.

<sup>&</sup>lt;sup>38</sup> https://www.cleanandclear.com/the-spot/benzoyl-peroxide-questions-answered (last accessed 3/21/2024).

<sup>&</sup>lt;sup>39</sup> https://www.neutrogena.com/the-bar/how-to-treat-acne-with-benzoyl-peroxide.html (last accessed 3/21/2024) (stating "[t]hat's where Benzoyl Peroxide 'comes in cue miracle entrance music.")

#### E. <u>Punitive Damages</u>

- 96. Defendants' conduct was done with malice and reckless disregard for human life. Defendants knew the BPO Products degraded to benzene when exposed to heat under normal consumer use, handling, and storage conditions. Defendants further knew that benzene is a known human carcinogen that is not supposed to be in the BPO Products due to the grave risk of harm to consumers. Defendants disregarded this information and the known risks of benzene exposure and deliberately omitted benzene from the list of ingredients, the BPO Products' labels, and their social media and websites where information about the BPO Products is found. Defendants consciously and deliberately crafted the BPO Products' marketing, labels, packaging, containers, and warnings intending to mislead Plaintiffs, the Class, and the public, and lead them to believe the BPO Products were safe and carcinogen-free.
- 97. Defendants marketed themselves as expert drug formulators, researchers, and merchandisers skilled in developing safe and reliable products while withholding material health and safety information Defendants knew were essential to informed consumer decision making. Defendants knew that, by their conduct, they were robbing consumers of their right to choose safe products.
- 98. Defendants were on notice of benzene findings in consumer and drug products leading to widely publicized recalls. Defendants were on notice of the FDA's concerns of benzene contamination in drug and consumer products and received the

FDA's 2022 directive to test Products for benzene contamination. Defendants disregarded these notices and continued to market and sell the BPO Products without testing them for benzene.

99 Defendants knew their decisions and chosen course of conduct was risky and would cause consumers to be exposed to benzene. Defendants' conduct was not by accident, but was deliberate, calculated, and informed. Defendants knew they could sell more BPO Products and earn more money by concealing material human health and safety information. Defendants further knew that testing the BPO Products for benzene would yield findings of benzene requiring recalls and/or a shutdown of production causing significant losses of income. Defendants' goals were met not only because of false and deceptive advertising, labeling, and packaging, but through a comprehensive scheme of aggressive marketing and image branding leading consumers to believe they were acne treatment experts dedicated to drug research, development, and safety and using only the safest ingredients and formulations that would remain pure and stable until the designated end. Defendants' conduct and concealment of material health information was done to further their own monetary gain and with conscious disregard of the Plaintiffs, the Class and the public's right to choose safe products. Defendants' conduct was intentional, calculated, blatantly deceptive, unscrupulous, and offensive to consumer health and public policy. To redress the harm caused by Defendants' conduct, Plaintiffs, on behalf of the Class, seek punitive damages against the Defendants.

#### F. <u>Injunctive Relief</u>

- 100. In the recent past, other products in the Defendants' health and beauty category of consumers goods have been contaminated with benzene, leading to a recall.
- Defendant to (1) purge any existing inventory of BPO intended for the use in products in their health and beauty category of consumers goods; (2) adopt new testing protocols requiring testing for the presence of benzene at no more than 2 parts per million (ppm) in products in their health and beauty category of consumers goods; (3) engage an independent, ISO-certified laboratory to test for benzene in random samples from at least 25% of manufactured lots in products in their health and beauty category of consumers goods; and (4) make those tests available to Plaintiffs and Class.
- 102. The injunctive relief would enable the Plaintiffs, the Class, and the wider public to choose safely from the Defendants' product offerings, specifically products the Defendants advertise as safe and high quality in their health and beauty category. Without it, the Plaintiffs' ability to choose safely from the offerings will be impaired or extinguished.

### PLAINTIFF-SPECIFIC ALLEGATIONS

103. At all times relevant, each Plaintiff, for his or her personal use, purchased a BPO Product made and sold by the Defendants under the Neutrogena brand. The Plaintiffs purchased the BPO Products in stores and online. They did so in this District

until moving to St. Louis, Missouri in 2022.

- 104. The BPO Products are premium products, and the Plaintiffs paid a premium price for them. The premium status and premium price are due to two factors: first, the iconic and beloved status of the Neutrogena and Clean & Clear brands (according to Defendants), and second, the marketing of Defendants, which was and is designed to influence consumers to believe that the BPO Products are expertly developed and tested by health leaders and are of very high quality and safe, warranting a premium price.
- 105. The Plaintiffs would not have paid a premium price for the BPO Products or used them if they had known of the benzene contamination and proven propensity of benzene contamination. Instead, they would have purchased and used less expensive, alternative acne treatments.
- 106. The BPO Products are not superior to alternative acne treatments, the premium price notwithstanding. They are inferior to alternative acne treatments which do not contain BPO and are not contaminated by benzene. There are many such alternative products. Valisure tested non-BPO acne products and found no benzene in them, not even at trace levels.
- 107. The Plaintiffs and the Class have suffered an ascertainable economic loss from their purchase and use of the BPO Products.
  - 108. Plaintiff Jones purchased the BPO Products in Kansas City, Missouri during

the time alleged. Specifically, she purchased and used "Neutrogena Rapid Clear Stubborn Acne Spot Gel," "Neutrogena On-the-Spot Acne Treatment," and "Neutrogena Clear Pore Cleanser/Mask." She has suffered economic harm from the Defendants' breaches and wrongful conduct, as alleged, including (but not limited to) their violations of the consumer protection law alleged herein. Plaintiff Jones never would have purchased Defendants' BPO Products had Defendants warned about the presence of benzene or that the Products would degrade into benzene from expected heat exposure. She would have purchased and used less expensive, alternative acne treatments which are not contaminated by benzene and are superior to the BPO Products for that reason.

- 109. Plaintiff Johnson purchased the BPO Products in Kansas City, Missouri during the time alleged. Specifically, he purchased and used "Neutrogena Rapid Clear Stubborn Acne Spot Gel," "Neutrogena On-the-Spot Acne Treatment," and "Neutrogena Clear Pore Cleanser/Mask." He has suffered economic harm from the Defendants' breaches and wrongful conduct, as alleged, including (but not limited to) their violations of the consumer protection law alleged herein. Plaintiff Johnson never would have purchased Defendants' BPO Products had Defendants warned about the presence of benzene or that the Products would degrade into benzene from expected heat exposure. He would have purchased and used less expensive, alternative acne treatments which are not contaminated by benzene and are superior to the BPO Products for that reason.
  - 110. Plaintiffs bring these claims for themselves and for a Class of similarly

situated persons in Missouri who purchased the BPO Products.

## EQUITABLE TOLLING OF STATUTES OF LIMITATIONS, CONCEALMENT, AND ESTOPPEL

- 111. Each purchase of a BPO Product constitutes a separate act that triggers anew the relevant statute of limitations.
- the delayed discovery doctrine, as Plaintiffs and the putative class members (defined below) did not and could not—through no fault or lack of diligence—reasonably have discovered Defendants' conduct alleged herein until shortly before the filing of this Complaint; and (2) the fraudulent concealment doctrine due to Defendants' knowing, purposeful, and active concealment and denial of all facts alleged herein including but not limited to their knowledge that the BPO contained in their Products degrades to benzene.
- 113. Defendants had exclusive knowledge that their BPO Products contained benzene and deceptively marketed their BPO Products to Plaintiffs, members of the Class, and the public.
- 114. Under the circumstances, Defendants had a duty to disclose the nature, significance, and consequences of the benzene contained in their BPO Products. Accordingly, Defendants is estopped from relying upon any statute of limitations.

#### **CLASS ACTION ALLEGATIONS**

115. Plaintiffs bring this case on behalf of themselves and all others similarly

situated as a Class Action under Rule 23 of the Federal Rules of Civil Procedure. Plaintiffs seek to represent a Class of individuals from Missouri who bought Defendants' BPO Products in Missouri for their personal use.

- 116. The Class does not seek damages for physical injuries, although each Plaintiff was physically harmed by being exposed to benzene.
- 117. The class is defined as: All persons in Missouri who bought, for use and not resale, the BPO Products of the Defendants within Missouri.
- 118. Excluded from this Class are Defendants, their employees, co-conspirators, officers, directors, legal representatives, heirs, successors, and affiliated companies; Class counsel and their employees; and judicial officers and their immediate families as court staff assigned to the case.
- 119. This action has been brought and may be properly maintained as a Class Action under Rule 23 of the Federal Rules of Civil Procedure because there is a well-defined community of interest and the proposed Class meets the class action requirements under Rule 23 of numerosity, commonality, typicality, and adequacy of representation.
- 120. Defendants engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiffs, on behalf of themselves and the other Class members. Similar or identical statutory and common law violations, business practices, and injuries are involved.

- 121. Numerosity. Plaintiffs believe there are at least thousands of Class members in Missouri, making the Class so numerous and geographically dispersed that joinder of all members is inconvenient and impracticable.
- 122. Commonality. There are questions of law and fact common to all Class members that predominate over questions which affect only individual Class members. All Class members were deceived and misled by Defendants through the same advertising, online representations, labeling, and packaging, which do not mention benzene and misrepresent the characteristics, ingredients, and safety of the BPO Products. All Class members bought Defendants' BPO Products and have suffered an economic loss because of Defendants' deceptions and omissions. Thus, there is a well-defined community of interest in the questions of law and facts common to all Class members. Other common questions of law and fact in this dispute include, without limitation:
  - a. Whether Defendants' BPO Products degrade to benzene under common distributor and consumer handling, use, and storage conditions.
  - b. Whether Defendants tested the BPO Products for benzene before selling them to Plaintiffs, the Class, and the public.
  - c. When Defendants knew or should have known the BPO Products degraded to benzene.
  - d. When Defendants knew or should have known the BPO Products contain benzene.
  - e. Whether Defendants' advertising omitting benzene was deceptive, fraudulent, or unfair.

- f. Whether Defendants' advertising omitting benzene was likely to deceive reasonable consumers.
- g. Whether Defendants' conduct violated the consumer protection law of Missouri.
- h. Whether Defendants breached the express and implied warranties made about their BPO Products.
- i. Whether Defendants was unjustly enriched by the Plaintiffs and the proposed Class members' purchase of the BPO Products.
- j. Whether the Plaintiffs and the proposed Class have been injured and if so, what is the proper measure of damages.
- k. Whether the Plaintiffs and the proposed Class have the right to economic damages including compensatory, exemplary, and statutory remedies for Defendants' misconduct.
- 1. Whether the Plaintiffs and the proposed Class have the right to injunctive, declaratory, or other equitable relief and attorneys' fees.
- 123. **Typicality**. Plaintiffs' claims are typical of the claims of the Class because the claims arise from the same course of misconduct by Defendants, i.e., Defendants' false and misleading advertising and their failure to disclose benzene in the Products. The Plaintiffs and members of the Proposed Class were all exposed to the same uniform and consistent advertising, labeling, and packaging statements Defendants made about the Products. Because of the Defendants' misconduct, Plaintiffs and Proposed Class were damaged and have incurred economic loss because of buying the Products believed to be safe. The claims of the Plaintiffs are typical of Class.
- 124. **Adequacy**. The Plaintiffs will fairly and adequately represent and protect the interests of all Class members. Plaintiffs have no interests antagonistic to the Class

members. Plaintiffs hired attorneys experienced in the prosecution of consumer Class Actions and Plaintiffs intend to prosecute this action vigorously. Plaintiffs anticipate no difficulty in the management of this litigation as a Class Action.

125. **Superiority.** Finally, this Class Action is proper under Rule 23(b) because, under these facts, a Class Action is superior to other methods and is the most efficient method for the fair and efficient adjudication of the dispute. The Class members have all suffered economic damages because of Defendants' deceptive trade practices, false advertising, and omissions of material health and safety information. Because of the nature of the individual Class members' claims and the cost of the Products, few, if any individuals, would seek legal redress against Defendants because the costs of litigation would far exceed any potential economic recovery. Absent a Class Action, individuals will continue to suffer economic losses for which they would have no remedy, and Defendants will unjustly continue their misconduct with no accountability while retaining the profits of their ill-gotten gains. Even if separate cases could be brought by individuals, the resulting multiplicity of lawsuits would cause undue hardship, burden, and expense for the Court and the litigants, as well as create a risk of inconsistent rulings across the country, which might be dispositive of the interests of individuals who are not parties. A Class Action furthers the important public interest of containing legal expenses, efficiently resolving many claims with common facts in a single forum simultaneously, and without unnecessary duplication of effort and drain on critical judicial resources. The

Class Action method presents far fewer management difficulties than individual cases filed in other districts and provides the benefit of comprehensive supervision by a single court.

#### CAUSES OF ACTION

### **COUNT I: BREACH OF EXPRESS WARRANTY**

- 126. Plaintiffs reallege and incorporate all other paragraphs in this Complaint and further allege:
- 127. Plaintiffs bring this cause of action on behalf of themselves and all members of the Class, all of whom are similarly situated consumers.
- 128. Plaintiffs, and each member of the Class, formed a contract with Defendants at the time Plaintiffs and the other Class Members purchased the BPO Products. The terms of the contract include the promises and affirmations of fact made by Defendants on the BPO Products' packaging and through marketing and advertising, specifically that the BPO Products were safe to use and did not contain any benzene. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and members of the Class, on the one hand, and Defendants, on the other hand.
- 129. Defendants expressly warranted that their BPO Products were fit for ordinary use, were merchantable, and were not misbranded. Defendants' express warranties were reflected in each BPO Product's labeling, promotions, and marketing

material, all of which uniformly identified BPO as the active ingredient and none of them identified benzene as an ingredient in Defendants' products. Defendants' product labeling and other materials were required to be truthful, accurate, and non-deceptive, but this was not the case as Defendants failed to disclose Plaintiff and members of the Class that their BPO Products contained benzene.

- 130. At all times relevant Missouri has codified and adopted the provisions of the Uniform Commercial Code. Mo. Rev. Stat. § 400.2-313.
- or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the promise. Defendants advertised and sold the Products as safe, pure, of good quality, and only containing the listed ingredients. Defendants' advertising, labels, containers, packaging, advertising, and online statements did not mention benzene, leading consumers to believe the Products were safe for their ordinary use. Defendants' affirmations were uniformly made to Plaintiffs and the Class members by Defendants in the Products' advertising, labeling, packaging, and online statements and were part of the basis of the bargain between Defendants, the Plaintiffs, and the Class.
- 132. Defendants' affirmations and promises are unlawful. When Defendants marketed, distributed, and sold the Products, Defendants knew, or should have known, the Products degraded to benzene under normal and expected use, handling, and storage

conditions. Defendants knew, or should have known, the Products formed benzene and therefore did not conform to Defendants' express representations and warranties to consumers. The Plaintiffs and Class members purchased the Products in reasonable reliance on Defendants' statements.

- 133. Defendants breached their express warranty because Defendants' BPO Products were not of merchantable quality, not fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.
- 134. Plaintiffs have provided Defendants with notice of their breach of warranty on behalf of themselves and all others similarly situated.
- 135. Plaintiff and members of the Class were reasonably expected purchasers of the misbranded and deceptively labeled BPO Products.
- 136. Because of Defendants' misconduct and breach of the express warranty, Plaintiffs, on behalf of themselves and the Class, seek recovery of their economic damages, attorneys' fees, punitive damages, restitution, and all other relief allowable by law, including an injunction to enjoin Defendants from continuing their fraudulent business practices. The damages sought are ascertainable, uniform to the Class and can be measured and returned to the Class members.

#### COUNT II: BREACH OF IMPLIED WARRANTY

137. Plaintiffs reallege and incorporate all other paragraphs in this Complaint and further allege:

- 138. Plaintiffs bring this cause of action on behalf of themselves, and all members of the Class, all of whom are similarly situated consumers.
- at the time Plaintiffs and the other Class Members purchased the BPO Products. The terms of the contract include the promises and affirmations of fact made by Defendants on the BPO Products' packaging and through marketing and advertising, specifically that the BPO Products were safe to use and did not contain any benzene. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiffs and members of the Class, on the one hand, and Defendants, on the other hand.
- 140. At all times relevant Missouri has codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability and fitness for ordinary purpose at Mo. Rev. Stat. § 400.2-314.
  - 141. Defendants were merchants within the meaning of the UCC.
- 142. Defendants' BPO Products constituted "goods" or the equivalent under the UCC. Defendants placed their BPO Products in sealed packaging or other closed containers and placed them on the market.
- 143. Defendants, as sellers of the Products, made implied warranties including warranting the Products were of the same quality and purity represented on the labels, in advertising, and on Defendants' websites and in advertising. Defendants represented

the Products were fit for the ordinary purpose and conformed to the promises made on the containers, labels, advertising, and websites that all ingredients were listed, and all warnings given.

- 144. Defendants advertised their Products as safe, when they knew, or should have known, the Products degraded to benzene. Defendants did not list benzene as an ingredient or contaminant anywhere on the Products or advertising. The Products are not of the quality and purity represented by Defendants because the Products degrade to benzene under normal use, handling, and storage conditions.
- 145. Defendants breached their implied warranty because Defendants' BPO Products were not of merchantable quality, not fit for the product's ordinary purpose, and did not conform to the standards generally applicable to such goods.
- 146. Plaintiffs have provided Defendants with notice of their breach of warranty on behalf of themselves and all others similarly situated.
- 147. Defendants did not tell the Plaintiffs or the Class members that the Products were not fit for their ordinary use because the Products, as advertised and sold by Defendants, degraded to benzene under normal and expected handling, use, and storage.
- 148. Defendants' affirmations that the Products were safe for use were uniformly made to the Plaintiffs and the Class members in the Products' advertising, labeling, and packaging, and on Defendants' websites, which were part of the basis of the bargain.

- 149. Plaintiffs and the Class members purchased the Products in reasonable reliance on Defendants' statements, affirmations, and omissions of material health and safety information.
- 150. Defendants' BPO Products did not fulfill their intended purpose as, instead of purchasing a safe treatment for acne, Plaintiff and members of the Class received products containing benzene, a dangerous human carcinogen.
- 151. Defendants' implied warranties were reflected in each BPO Product's labeling, promotions, and marketing material, all of which uniformly identified BPO as the active ingredient and none of them identified benzene as an ingredient in Defendants' products. Defendants' product labeling and other materials were required to be truthful, accurate, and non-deceptive, but this was not the case as Defendants failed to disclose Plaintiff and members of the Class that their BPO Products contained benzene.
- 152. Plaintiffs and members of the Class were the intended third-party beneficiary recipients of all arrangements Defendants had with downstream resellers of Defendants' BPO Products. Plaintiffs and each member of the Class were those whose benefit any promises, affirmations, or warranties were made by Defendants concerning the BPO Products, as they were the end purchasers of Defendants' BPO Products, which Defendants knew by virtue of their position as manufacturer and seller of the BPO Products.
  - 153. Defendants' acts and omissions are ongoing and continuing to cause harm.

154. As a direct and proximate result of Defendants' misconduct, Plaintiffs, on behalf of themselves and the Class members, seek recovery of their actual damages, injunctive relief, attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are uniform to the Class and the actual damages can be measured and returned to consumers who bought Defendants' Products.

## **COUNT III: UNJUST ENRICHMENT**

- 155. Plaintiffs reallege and incorporate all other paragraphs in this Complaint and further allege:
- 156. Plaintiffs bring this cause of action on behalf of themselves and all members of the Class, all of whom are similarly situated consumers.
- 157. Defendants have unjustly profited from their deceptive business practices and kept the profits from Plaintiffs and the Class members who purchased the Products.
- 158. Defendants requested and received a measurable economic benefit at the expense of Plaintiffs and the Class members as payment for the Products. Defendants accepted the economic benefits knowing the economic benefit received was based on deception and omission of material human health and safety information.
- 159. There is no utility in Defendants' misconduct and Defendants' enrichment from the misconduct is unjust, inequitable, unconscionable, and against the strong public policy to protect consumers against fraud.
  - 160. Because of Defendants' misconduct, Plaintiffs, on behalf of themselves, the

Class, and the public seek recovery of their actual damages, disgorgement of profits, injunctive relief, attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are uniform to the Class and the actual damages can be measured and returned to consumers who bought Defendants' Products.

## **COUNT IV: FRAUD**

- 161. Plaintiff re-alleges and incorporates the preceding paragraphs as if fully set forth herein.
- 162. Defendants affirmatively misrepresented material facts, including, *interalia*, the fact that their BPO Products contained benzene.
- 163. Defendants omitted material facts including, *inter alia*, that the BPO Products contained benzene.
- 164. Defendants' actions had the effect of fraudulently inducing customers—including Plaintiffs and members of the Class—to pay for Defendants' BPO Products, which Defendants knew or should have known contained a human carcinogen, benzene, and were misbranded. Plaintiffs and members of the Class would not have purchased Defendants' BPO Products had they known the truth. Indeed, Plaintiffs and members of the Class *could not* have purchased Defendants' BPO Products, because the inclusion of benzene renders those products as illegally manufactured, imported, distributed, and sold.
  - 165. Defendants knowingly, or at least recklessly, represented that their BPO

Products did not contain benzene through their labeling, marketing, advertising, and promotion.

- 166. Defendants knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading.
- 167. Defendants knew, or had reason to know, that their misrepresentations and omissions would induce Plaintiffs and members of the Class to purchase Defendants' BPO Products.
  - 168. Defendants' misrepresentations and omissions were material.
- 169. Defendants actively concealed their misrepresentations and omissions from Plaintiffs, members of the Class, and the public.
- 170. Defendants intended their misrepresentations and omission to induce Plaintiffs and members of the Class to purchase Defendants' BPO Products.
- 171. But for these misrepresentations and omissions, Plaintiffs and members of the Class would not have purchased Defendants' BPO Products.
- 172. To the extent applicable, Plaintiffs and members of the Class were justified in relying on Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated to each member of the Class through, *inter alia*, product labeling and packaging, as well as Defendants' marketing and promotional material. No reasonable consumer would have purchased

Defendants' BPO Products but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

- 173. Plaintiffs and members of the Class were damaged by reason of Defendants misrepresentations and omissions alleged herein.
- 174. Defendants intended their misrepresentations or omissions to induce Plaintiffs and members of the Class to purchase Defendants' BPO Products, or had reckless disregard for the same.
- 175. As a direct and proximate result of Defendants' acts and omissions described herein, Plaintiffs and members of the Class have suffered harm and will continue to do so.
- 176. Defendants' misrepresentations or omissions were material and a substantial factor in the decision of Plaintiffs and members of the Class to purchase Defendants' BPO Products.
- 177. Defendants intended their misrepresentations or omissions to induce Plaintiff and members of the Class to purchase their BPO Products or had reckless disregard for same.
- 178. But for these misrepresentations (or omissions), Plaintiff and members of the Class would not have made purchases of Defendants' BPO Products.
- 179. To the extent applicable, Plaintiffs and members of the Class were justified in relying on each of Defendants' misrepresentations and omissions. The same or

substantively identical misrepresentations and omissions were communicated to each member of the Class through, *inter alia*, product labeling and packaging, as well as Defendants' marketing and promotional material. No reasonable consumer would have purchased Defendants' BPO Products but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.

180. Plaintiffs and members of the Class were damaged by reason of Defendants' misrepresentations or omissions alleged herein.

### **COUNT V: NEGLIGENT MISREPRESENTATION AND OMISSION**

- 181. Plaintiff realleges and incorporates the preceding paragraphs as if fully set forth herein.
- 182. Defendants had or undertook a duty to accurately represent the ingredients of their BPO Products.
- 183. Defendants failed to exercise ordinary care in making representations (or in failing to disclose facts) concerning the ingredients of their BPO Products.
- 184. Defendants negligently misrepresented or omitted facts regarding the ingredients of their BPO Products.
- 185. Defendants' misrepresentations or omissions regarding the ingredients of their BPO Products occurred in the products' labeling and packaging as well as in the marketing and promotional material for their BPO Products.
  - 186. Defendants' statements were false at the time the misrepresentations were

made (or at the time omissions were not made).

187. Defendants knew, or reasonably should have known, that their representations alleged herein were materially false or misleading, or that omissions of material facts rendered such representations false or misleading. Defendants also knew, or had reason to know, that their misrepresentations and omissions would induce Plaintiff and the members of the Class to purchase their BPO Products.

## COUNT VI: VIOLATION OF MISSOURI MERCHANDISING PRACTICE ACT

- 188. Plaintiff realleges and incorporates the preceding paragraphs as if fully set forth herein.
- 189. The Missouri Merchandising Practice Act, Mo. Rev. Stat. § 407.010, et seq. ("MMPA") prohibits "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Rev. Stat. § 407.020(1).
- 190. Defendants' conduct constitutes "trade or commerce" within the meaning of Mo. Rev. Stat. § 407.020(1).
- 191. Plaintiffs and members of the Class acted as a "reasonable consumer" within the meaning of Mo. Rev. Stat. § 407.025(2)(a) and is a "person" as envisioned in Mo. Rev. Stat. § 407.025(1).
  - 192. Defendants' conduct as alleged herein—to wit, knowingly concealing or

failing to disclose the presence of benzene in their BPO Products—constitutes deception, fraud, false pretense, false promise, misrepresentation, unfair practice and/or the concealment, suppression, or omission of material facts in connection with the sale or advertisement of merchandise in trade or commerce in violation of the MMPA. Defendants' conduct was intended to cause a reasonable person to purchase their products and did, in fact, cause reasonable persons including Plaintiffs and members of the Class to purchase their products. Had Defendants fully disclosed the presence of benzene in their BPO Products Plaintiffs and members of the Class would not have purchased those products.

- 193. Plaintiffs have provided Defendants with notice of their claim on behalf of themselves and all others similarly situated.
- 194. To the extent applicable, Plaintiffs and members of the Class were justified in relying on each Defendants' misrepresentations and omissions. The same or substantively identical misrepresentations and omissions were communicated to each member of the Class through, *inter alia*, product labeling and packaging, as well as Defendants' marketing and promotional material. No reasonable consumer would have purchased Defendants' BPO Products but for Defendants' unlawful conduct. To the extent applicable, reliance may be presumed in these circumstances.
- 195. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and members of the Class

seek recovery of their economic damages, attorneys' fees, punitive damages, restitution, and all other relief allowable by law, including an injunction to enjoin Defendants from continuing their fraudulent business practices. The damages sought are ascertainable, uniform to the Class and can be measured and returned to the Class members.

## PRAYER FOR RELIEF

For these reasons, Plaintiffs pray for the following judgment:

- A. An order certifying this action as a class action;
- B. An order appointing Plaintiffs as Class Representatives, and appointing undersigned counsel as Class Counsel to represent the Class;
- C. A declaration that Defendants is liable under each and every one of the above enumerated causes of action;
- D. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described above;
- E. Payment to Plaintiffs and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid for the BPO Products; and/or the costs to replace or return the BPO Products;
- F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;
- G. An award of statutory penalties to the extent available;
- H. Interest as provided by law, including but not limited to pre-judgment and post judgment interest as provided by rule or statute; and
- I. Such other and further relief as this Court may deem just, equitable, or proper.

Dated: July 31, 2024

# Respectfully submitted,

## PAUL LLP

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